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Case Report

Perclose Closure Device breakage and embolization during deployment followed by retrieval with snare

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ABSTRACT

Perclose Closure Device (Abbott-Vascular) was attempted for femoral artery (FA) access site closure by an experienced operator. The device was felt to snap as it was pushed through the previously scarred skin and subcutaneous tissue. Perclose had broken into two pieces with the proximal portion outside the body and the distal portion embolizing to lie in the FA to distal aorta. The left FA was accessed through 8F sheath and 4–8 mm Basket snare passed through a 6F multipurpose guiding catheter. The tip of the broken Perclose was caught with the snare and pulled out. The Perclose has a distal flexible sheath that is overmolded directly onto the proximal rigid guide. This junction of sheath and guide may be a weak point. Accidental pressure applied at this weak point in any Perclose device during deployment can cause breakage. Awareness of this rare complication is important for safety.

1. Introduction

Closure devices are widely used in femoral access cardiovascular procedures for early ambulation and potential morbidity reduction.[1] Perclose ProGlide is a suture mediated closure device (Abbott-Vascular, Redwood City, CA). This closure device uses a polyester pretied suture knot to close an arteriotomy site after cardiovascular procedures. It is approved for the closure of 5 French to 8 French sheaths using a single Perclose device with the standard technique and larger sheaths up to 21 French using two Perclose devices with the Perclose technique.[2] The device has demonstrated excellent safety record in large series.[3]

2. Case report

A 76-year-old male presented with shortness of breath and congestive heart failure Class IV. Right and left heart catheterization confirmed severe pulmonary hypertension, severely elevated pulmonary capillary wedge pressure, normal left ventricular ejection fraction, and severe aortic stenosis. The right femoral artery had been used for arterial access and the femoral vein had been used for venous access. A sheath angiogram revealed that the 6 French (F) sheath was in a large femoral artery that was over 8 mm in diameter and this appeared to be either common femoral or proximal superficial femoral on sheath angiogram. The patient had severe

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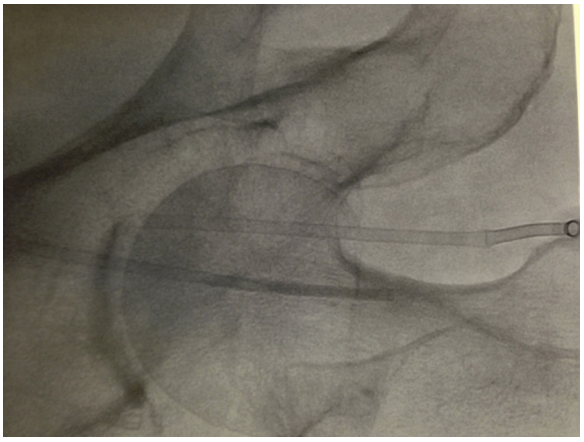

Fig. 1 – Long broken piece of Perclose device seen next to venous sheath.

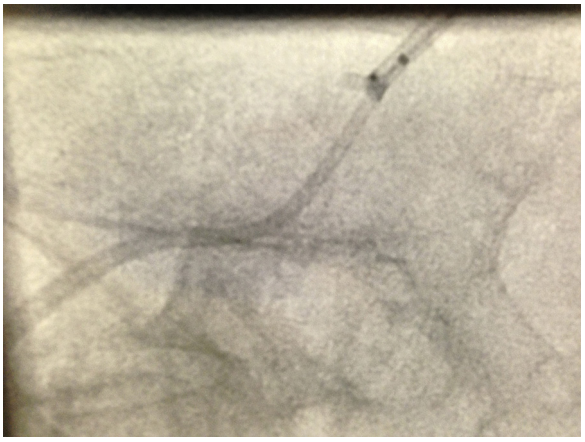

Fig. 3 – Broken Perclose sheath being pulled out with snare.

orthopnea so device closure rather than manual pressure hemostasis was chosen at the conclusion of the procedure. An operator who had personally deployed over 5000 Perclose devices with no significant complications attempted the right femoral artery for closure with Perclose.[3] The standard technique was used as the 0.035 in. guidewire was removed and the Perclose device was pushed through the patient's skin, previously scarred subcutaneous tissue and femoral arterial wall when the Perclose was felt to snap into two pieces. The Perclose device has the long flexible sheath, which attaches to the rigid thick guide that houses the needles and the sutures.[2] The device had broken into two pieces at the junction of the sheath and the guide with the long distal flexible sheath free floating from the common femoral artery to the distal aorta but not embolizing further distally (Fig. 1). A plan was made to retrieve the embolized broken distal sheath with a snare as the proximal guide was still outside the body. We placed an 8F sheath through the left femoral artery and in order to facilitate snare passage, placed a Multipurpose A1 guiding catheter (Cordis Corporation, Fremont, CA) over a 0.038 in. guidewire into the distal aorta. Several snares were then tried to retrieve the broken distal Perclose sheath. The snares tried, which were unable to grab the broken sheath, were 18–30 mm Basket snare (Cook Medical, Bloomington, IN, USA) and a 7 mm Gooseneck snare (Covidien, Minneapolis, MN, USA). After this, a 4–8 mm Basket snare was sent through the Multipurpose A1 guiding catheter and successfully grabbed the broken Perclose sheath. The snare, the Multipurpose guide, and the sheath were removed as one unit (Figs. 2 and 3). V+ pads (Argon Medical Devices, Plano, TX, USA) were used on both groins to assist with hemostasis.

The patient had no additional complications from the Perclose embolization and retrieval. The same operator has placed over 2000 additional Perclose devices since then and no repeat device breakage has been observed.

3. Discussion

We report a rare but significant potential complication of Perclose device. We have previously reported the largest single operator experience with Perclose device in the world and have noted this closure device's safety and effectiveness.[3] The Perclose device has a distal portion that is flexible and is called the sheath and is made up of polyether block amide. It is overmolded directly onto the proximal rigid portion of the

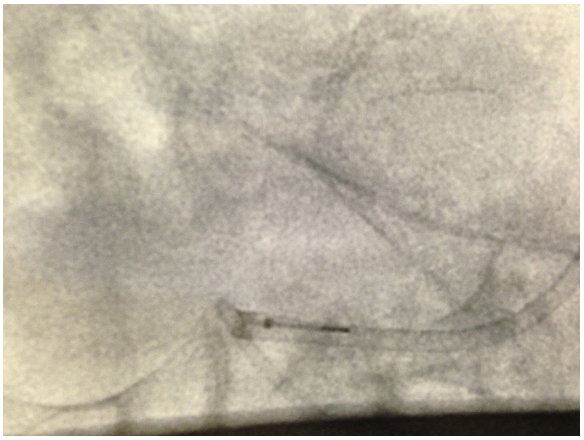

Fig. 2 – Broken Perclose sheath in distal aorta grabbed with a snare.

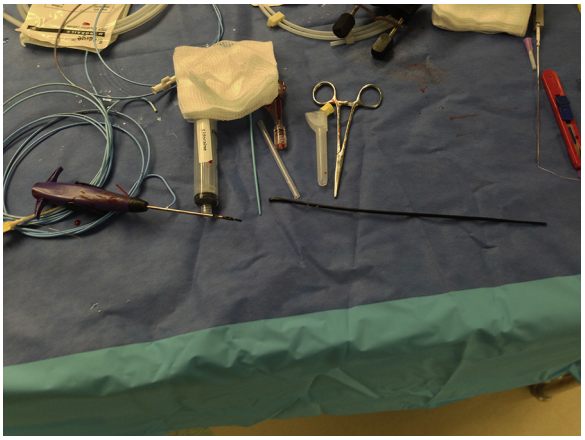

Fig. 4 – Broken device at the junction of distal sheath with proximal guide.

device that is called the guide to make a seamless transition.[2] The Perclose device has a weak point at the junction of the sheath and guide and any Perclose device can be broken outside the body with minimal effort (Fig. 4, Video 1). This video replicates what we have seen many times outside the body that by applying mild force at the junction of the guide and the sheath, the Perclose snaps into two pieces. This suggests that the Perclose breakage in the case reported here was not an isolated event due to some unique manufacturing defect in a single Perclose item or due to overconfidence of the operator but is due to the weak point at the sheath and guide junction in all Perclose products. The way to avoid it is to be aware of the location of weak point and when pushing the device, avoidance of significant force at that site. This particular case reported here was possibly contributory to the change in ''Instructions for Use'' because at the time of this breakage of Perclose in our patient several years ago, such caution about risk of breakage was not noted in the ''Instruction for Use'' by us but after our report to the company, such an amendment has been noted in the ''Instruction for Use'' document.[2] This case of Perclose breakage was never reported before in a publication form by us nor have we seen any other case reports of similar Perclose breakage. As noted, Perclose is an extremely safe product but users should be aware of this possible complication and the way to treat it with snare retrieval.

Supplementary Video 1 related to this article can be found, in the online version, at doi:10.1016/j.ihj.2015.08.024.

Conflicts of interest

The authors have none to declare.

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